DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
C/O SUSAN GOLDSTEIN-FALK
MDI CONSULTANTS, INC.
55 NORTHERN BLVD., SUITE 200
GREAT NECK, NY 11021

September 2, 2014

Re: K140690
Trade/Device Name: BS-480/BS490/CLC720i Chemistry Analyzer
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea nitrogen test system
Regulatory Class: II
Product Code: CDQ, JGS, CEM, CGZ, JJE
Dated: July 25, 2014
Received: July 28, 2014

Dear Ms. Susan Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k140690

Device Name
BS-480/BS-490/CLC720i Chemistry Analyzer

Indications for Use *(Describe)*
The BS-480/BS-490/CLC720i chemistry analyzer is designed for clinical laboratory use, making direct quantitative measurements of Na+ (sodium), K+ (potassium), Cl-(chloride) in serum, plasma and urine samples and Urea Nitrogen in serum samples. Additionally, other various chemistry tests may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.
Sodium measurements are used in the diagnosis and treatment diseases involving electrolyte imbalance.
Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.
Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.
Urea Nitrogen (BUN) measurements are used to aid in the determination of liver and kidney functions and other diseases associated with protein catabolism.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: _K140690___.

Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 2658 2888
Fax: +86 755 2658 2680

- **Contact Person:**

Tan Chuanbin
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

- **Date Prepared:**

February 20, 2014

Name of the device:

- **Trade/Proprietary Name:** BS-480 Chemistry Analyzer, BS-490 Chemistry Analyzer, CLC720i Chemistry Analyzer
  (BS-480, BS-490 and CLC720i are the same analyzers except the Models. For convenience of explanation, the BS-480 Chemistry Analyzer is represented of the three in this summary.)

- **Common Name:** Clinical Chemistry Analyzer (with optional ISE Module)

- **Classification Number/Class:**
  75JJE, Class Ⅰ
  75CDQ, Class Ⅱ
  75CEM, Class Ⅱ

75CGZ, Class Ⅱ
75JGS, Class Ⅱ

Legally Marketed Predicate Device:

K112377 BS-400 Chemistry Analyzer, Mindray
K971309 UREA, DERMA MEDIA LAB., INC.

Description:

The BS-480/BS-490/CLC720i Chemistry Analyzer is an automated clinical chemistry analyzer capable of performing various in vitro photometric assays. The UREA was cleared under K971309 and is the chosen assay to demonstrate performance for the photometric unit. The BS-480 Chemistry Analyzer has an optional Ion-Selective Electrode (ISE) module which measures the concentration of the electrolytes, sodium, potassium, and chloride, in samples using ion selective electrode technology.

Intended Use/ Indication for Use:

The BS-480/BS-490/CLC720i chemistry analyzer is designed for clinical laboratory use, making direct quantitative measurements of Na^+ (sodium), K^+ (potassium), Cl^-(chloride) in serum, plasma and urine samples and Urea Nitrogen in serum samples. Additionally, other various chemistry tests may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.
Sodium measurements are used in the diagnosis and treatment diseases involving electrolyte imbalance.
Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.
Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.
Urea Nitrogen (BUN) measurements are used to aid in the determination of liver and kidney functions and other diseases associated with protein catabolism.

Comparison of Technological Characteristics:

Substantial equivalence has been demonstrated between the BS-480 Chemistry Analyzer and BS-400 Chemistry Analyzer. Both of them utilize absorbance photometry to perform and output quantitative results for kinetic and endpoint clinical chemistries. For analytes, BS-480 Chemistry Analyzer and BS-400 Chemistry Analyzer determine the concentration of unknown samples from a standard curve generated with known analyte concentrations. The BS-480 Chemistry Analyzer and BS-400 Chemistry Analyzer both utilize Ion-Selective Electrodes technology and are equipped with the same ISE Module.

Performance Characteristics:

Performance testing of the BS-480 Chemistry Analyzer consisted of running the FDA previously cleared assay and the ISE module on the BS-480 to evaluate precision, linearity, and method comparison, Limits of Detection and Limits of Quantitation, interference, ISE plasma sample type studies.

A correlation analysis between the BS-480 Chemistry Analyzer and BS-400 Chemistry Analyzer yielded the following results:

Analyte	Unit	Sample Range	N	Slope	Intercept	Correlation Coefficient
BUN	mg/dL	5.7-147.4	120	0.9912	0.0494	1.000
Serum Na^+	mmol/L	101.3-197.1	132	0.9613	3.243	0.998
Serum K^+	mmol/L	1.35-7.34	120	0.9570	0.0914	1.000
Serum Cl^-	mmol/L	54.7-147	125	0.9537	4.216	0.998
Urine Na^+	mmol/L	12-473	120	0.9925	-0.9291	1.000
Urine K^+	mmol/L	5-192	120	0.9677	0.6774	1.000
Urine Cl^-	mmol/L	16-396	120	1.006	2.704	1.000

And the bias at the medical decision points of method comparison yielded the following results:

Analyte	Unit	Medical decision points	Bias at the medical decision points (Difference/Difference%)		
			Point 1	Point 2	Point 3
BUN	mg/dL	6, 26, 50	0.00/-0.1%	-0.18/-0.7%	-0.39/-0.8%
Serum Na^+	mmol/L	115,135,150	-1.26/-1.1%	-2.0/-1.5%	-2.55/-1.7%
Serum K^+	mmol/L	3.0, 5.8, 7.5	-0.038/-1.3%	-0.158/-2.7%	-2.31/-3.1%
Serum Cl^-	mmol/L	90,112	0.05/0.1%	-0.97/-0.9%	/
Urine Na^+	mmol/L	40,112	-1.2/-3.1%	-2.6/-1.2%	/
Urine K^+	mmol/L	25,125	-0.1/-0.5%	-3.4/-2.7%	/
Urine Cl^-	mmol/L	110,250	3.4/3.1%	4.2/1.7%	/

The preliminary precision test of BS-480 yielded the following results:

Analyte	Unit	Level	Mean	SD	CV%
BUN	mg/dL	Control pool 1	16.1	0.13	0.8%
		Control pool 2	41.6	0.41	1.0%
		Control pool 3	66.5	0.33	0.5%
		Patient pool 1	8.8	0.09	1.0%

		Patient pool 2	20.4	0.09	0.4%
		Patient pool 3	41.3	0.16	0.4%
Serum Na^+	mmol/L	Control pool 1	140.5	0.35	0.3%
		Control pool 2	158.0	0.27	0.2%
		Control pool 3	117.0	0.28	0.2%
		Patient pool 1	114.6	0.37	0.3%
		Patient pool 2	128.0	0.42	0.3%
		Patient pool 3	154.1	0.87	0.6%
Serum K^+	mmol/L	Control pool 1	3.69	0.010	0.3%
		Control pool 2	5.58	0.015	0.3%
		Control pool 3	2.79	0.010	0.4%
		Patient pool 1	2.93	0.007	0.2%
		Patient pool 2	5.45	0.021	0.4%
		Patient pool 3	7.19	0.032	0.4%
Serum Cl^-	mmol/L	Control pool 1	103.1	0.37	0.4%
		Control pool 2	124.7	0.28	0.2%
		Control pool 3	83.0	0.26	0.3%
		Patient pool 1	88.6	0.30	0.3%
		Patient pool 2	117.0	0.69	0.6%
Urine Na^+	mmol/L	Control pool 1	74	0.9	1.3%
		Control pool 2	165	2.4	1.4%
		Patient pool 1	41	0.3	0.8%
		Patient pool 2	203	0.5	0.2%
Urine K^+	mmol/L	Control pool 1	34	0.4	1.3%
		Control pool 2	96	0.4	0.5%
		Patient pool 1	26	0.0	0.0%
		Patient pool 2	119	0.5	0.4%
Urine Cl^-	mmol/L	Control pool 1	71	1.1	1.5%
		Control pool 2	199	1.5	0.7%
		Patient pool 1	113	1.1	0.9%
		Patient pool 2	246	0.9	0.4%

The total precision test of BS-480 yielded the following results:

Analyte	Unit	Sample	n	Mean	Repeatability		Within-Device Precision	
					SD	CV%	SD	CV%
BUN	mg/dL	Control pool 1	80	16.0	0.12	0.7%	0.28	1.7%
		Control pool 2	80	41.3	0.18	0.4%	0.70	1.7%

		Control pool 3	80	66.4	0.30	0.5%	1.18	1.8%
Serum Na^+	mmol/L	Control pool 1	80	142.2	0.51	0.4%	1.15	0.8%
		Control pool 2	80	159.9	0.35	0.2%	1.02	0.6%
		Control pool 3	80	118.5	0.25	0.2%	0.81	0.7%
Serum K^+	mmol/L	Control pool 1	80	3.70	0.01	0.4%	0.03	0.9%
		Control pool 2	80	5.64	0.02	0.3%	0.04	0.7%
		Control pool 3	80	2.78	0.01	0.4%	0.02	0.8%
Serum CL^-	mmol/L	Control pool 1	80	102.6	0.53	0.5%	0.93	0.9%
		Control pool 2	80	125.0	0.43	0.3%	0.86	0.7%
		Control pool 3	80	82.3	0.40	0.5%	0.67	0.8%
Urine Na^+	mmol/L	Control pool 1	80	75	1.29	1.7%	2.21	2.9%
		Control pool 2	80	165	1.75	1.1%	2.93	1.8%
Urine K^+	mmol/L	Control pool 1	80	34	0.16	0.5%	0.49	1.5%
		Control pool 2	80	97	0.34	0.3%	0.77	0.8%
Urine Cl^-	mmol/L	Control pool 1	80	76	0.89	1.2%	2.02	2.7%
		Control pool 2	80	202	1.20	0.6%	2.32	1.1%

The linearity test of BS-480 yielded the following results:

Analyte	Unit	Slope	Intercept	Correlation Coefficient	Linear Range Tested	Claimed Linear Range
BUN	mg/dL	1.0000	-0.0109	0.9992	5.1-165.1	5.5-151.7
Serum Na^+	mmol/L	1.0001	-0.0073	0.9999	69.1-250.2	100-200
Serum K^+	mmol/L	1.0001	-0.0005	0.9998	0.85-9.76	1-8
Serum Cl^-	mmol/L	0.9999	-0.0126	0.9999	44.7-186.1	50-150
Urine Na^+	mmol/L	1.0001	-0.0461	1.0000	10-614	10-500
Urine K^+	mmol/L	1.0005	-0.2565	0.9997	4-230	5-200
Urine Cl^-	mmol/L	1.0000	-0.2015	0.9996	7-452	15-400

The detection limit studies test of BS-480 yielded the following results:

Analyte	Unit	LoB	LoD	LoQ
BUN	mg/dL	0.2	0.3	4.8
Serum Na^+	mmol/L	3.7	5.1	48.0
Serum K^+	mmol/L	0.21	0.24	0.69
Serum Cl^-	mmol/L	1.2	3.7	36.6

Urine Na^+	mmol/L	3	4.5	10
Urine K^+	mmol/L	1	1.2	3.3
Urine Cl^-	mmol/L	1	2.6	6.3

The Interference test of BS-480 yielded the following results:
Effects of bilirubin, hemoglobin, lipemia, ascorbic acid are tested. There is no significant interference (NSI) observed when the concentrations of interference materials is below the ones in the following table

Item	Interference materials (mg/dL)			
	Bilirubin	Hemoglobin	Lipemia	ascorbic acid
BUN	40	500	1000	30
Serum Na^+	40	500	1000	30
Serum K^+	40	/	1000	30
Serum Cl^-	40	500	1000	30
Urine Na^+	40	500	1000	30
Urine K^+	40	125	1000	30
Urine Cl^-	40	250	1000	30

* For Potassium, hemolysis can lead to falsely elevated K^+ values, so there is no claimed NSI concentration of hemoglobin to Serum K^+.

The Interference test of BS-480 yielded the following results:
There was no significant interference for these drugs, when these analytes and interferents were tested in the concentration ranges indicated below:

Drug interferents	Drug level tested(mg/dL)
Imipramine	0.15
Procainamide	15
Nortriptyline	0.23
Hydroxytyramine	50.4
Valproic acid	75.5
Chlorpromazine	6
Salicylic acid	70.5
Acetylsalicylic acid	1201
Erythromycin	7.1
Ethosuximide	30.5
Acetaminophen	242
Ampicillin	6

There was significant interference for Ibuprofen, Benzalkonium Chloride and Potassium thiocynate, when these analytes and interferents were tested in the concentration ranges indicated below:

Drug interferents	ISE application	Drug level tested(mg/dL)	Effect
Ibuprofen	Serum K^+	506	Decreases Potassium by 0.5mmol/L at the concentration of 3.25 mmol/L and by 0.59 mmol/L at the concentration of 5.39 mmol/L;
	Serum Cl^-	380	Increases Chloride by 15.4 mmol/L at the concentration of 99 mmol/L and by14.6 mmol/L at the concentration of 119.3 mmol/L
Benzalkonium Chloride	Serum Na^+	7.7	Increases Sodium by 21.5 mmol/L at the concentration of 130.5 mmol/L and by 17.4 mmol/L at the concentration of 146.1 mmol/L;
	Serum K^+	5.2	Increases Potassium by 0.38 mmol/L at the concentration of 2.97 mmol/L.
Potassium thiocynate	Serum K^+	6.1	Increases Potassium by 0.71 mmol/L at the concentration of 2.97 mmol/L and by 0.65 mmol/L at the concentration of 5.08 mmol/L;
	Serum Cl^-	12.2	Increases Chloride by 13.4 mmol/L at the concentration of 90.1 mmol/L and by14.4 mmol/L at the concentration of 111.2 mmol/L.

The BS-480's sample type studies between serum and plasma of Na^+, K^+, Cl^- test yielded the following results, which proved the sample type plasma can also apply to ISE test:

Analyte	Unit	N	Sample Range	Slope	Intercept	Correlation Coefficient
Na^+	mmol/L	67	103.2-185.5	0.971	2.9	0.995
K^+	mmol/L	67	1.2-6.9	0.974	-0.17	0.992
Cl^-	mmol/L	67	70.4-143.2	1.005	-0.1	0.995

Conclusion:

The data demonstrates that the BS-480 Chemistry Analyzer is substantially equivalent to BS-400 Chemistry Analyzer.